UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FEDERAL TRADE COMMISSION, STATE OF ILLINOIS, and STATE OF MINNESOTA, Plaintiffs, v. GTCR, LLC, GTCR BC HOLDINGS, LLC, and SURMODICS, INC., Defendants.	)	No. 25 C 2391 Judge Cummings

NON-PARTY FDA'S MEMORANDUM IN OPPOSITION TO GTCR'S MOTION TO COMPEL AND IN SUPPORT OF ITS MOTION TO QUASH

Introduction

This case began when the Federal Trade Commission and several states filed suit to enjoin a merger between GTCR and another company, alleging that it would substantially lessen competition in the marketplace. But FDA — the party subject to the subpoena at issue here — is not involved in this litigation and is *not* a party to this suit. Even so, defendant GTCR moves to compel FDA to spend *millions* of agency hours to comply with its subpoena. GTCR seeks nearly one hundred thousand separate medical device submissions (each submission contains thousands of pages) that contain trade secret information and confidential commercial information protected from disclosure. FDA staff would need millions of hours to review and redact such information. This hour estimate is not an exaggeration, as will be explained with actual calculations below. Additionally, the subpoena conflicts with FDA's *Touhy* regulations at 21 C.F.R. Part 20, which were promulgated *specifically* to avoid this very situation—draining the agency's resources in a manner that does not serve the interest of FDA or the public health. Finally, because third-party information owners sent these records to FDA, GTCR should seek information from those third parties, who are the complete and accurate source of the requested information.

Background

The Federal Trade Commission ("FTC") along with the States of Illinois and Minnesota filed suit on March 6, 2025, seeking a preliminary injunction to enjoin a proposed merger of defendants GTCR BC Holdings, LLC ("GTCR")[1] and Surmodics, Inc. *See* Dkt. 1. On April 14, 2025, GTCR served FDA, a non-party in the underlying action, with a subpoena *duces tecum* ("GTCR's Subpoena" or "Subpoena") that seeks *all* Premarket Approval ("PMA"), De Novo, and 510(k) submissions, including supplement and master file ("MAF") submissions, (collectively "submissions") received by FDA from January 1, 2010, through the present, for medical devices that may use a lubricious coating. *See* Dkt. 154, Mot. to Compel at 2-3. GTCR filed a motion to compel on June 18, 2025, demanding FDA's compliance with the Subpoena.[2] *See* Dkt. 154.

Upon receipt of GTCR's Subpoena on April 22, 2025, FDA timely responded to GTCR pursuant to Fed. R. Civ. P. 45(d)(2)(B) with written objections, including, but not limited to, that: (1) the requested documents contained trade secret information ("TSI") and confidential commercial information ("CCI"); (2) the requested documents could be more easily and efficiently obtained through other sources; (3) the subpoena is overly broad and unduly burdensome in that the production would strain FDA's resources because it would require a significant amount of time to collect, review, and produce documents in litigation which FDA is not a party; and (4) the

[1] This action is brought against GTCR, LLC, GTCR BC Holdings, LLC, and their affiliates and subsidiaries.

[2] GTCR should have filed its motion to compel in the district where compliance is required, the District of Maryland or the District of Columbia. Movant relies on 12 U.S.C. § 23 for jurisdiction. Dkt. 154, Mot. to Compel at 6 n.3. Section 13 of the Clayton Act does not displace Fed. R Civ. P. 45(d)(2)(B)(i)'s requirement that the serving party "move the court for the district where compliance is required for an order compelling production or inspection."

subpoena seeks information that is neither relevant nor proportional to the needs of the case.[3] Exhibit A, Rule 45 Letter.

On April 29, 2025, FDA counsel met and conferred with GTCR's counsel. Subsequent discussions occurred on May 16, 2025, and May 28, 2025.[4] During the course of these discussions, FDA continually emphasized that GTCR requested an excessive number of documents, and that FDA does not have the resources to search, collect, review, redact, and process this extreme volume of documents in third-party litigation cases, which would divert significant resources from FDA's public health mission. During these conversations, GTCR suggested limiting the requested documents to submissions of the product codes listed in Appendix A of the Subpoena. On May 28, 2025, FDA explained that even if GTCR's Subpoena was limited to product codes listed in Appendix A of the Subpoena, there would still be over ten thousand submissions for FDA staff to search, collect, review, redact, and process.

FDA reiterated that even if its staff could retrieve the requested documents, information on lubricious coatings (*e.g.*, supplier information) would likely be trade secret information and/or confidential commercial information. Accordingly, not only would it take FDA an unconscionable amount of time to redact the documents but would also result in the purportedly relevant parts of the documents being redacted, which would render them basically useless. Further, FDA explained repeatedly that it is not a "complete source" of the information that GTCR seeks regarding suppliers of lubricious coatings. Dkt. 154, Mot. to Compel at 7. Information owners (*e.g.*,

[3] FDA reserved the right to raise additional objections at a later time. *See* April 22, 2025, Letter at 1 n.1.

[4] FDA disagrees with GTCR's characterizations of the May 28, 2025, conversation. GTCR notes that "FDA agreed the protective order is robust, but claimed that its own *Touhy* rules prohibit it from disclosing the submissions." Dkt. 154, Mot. to Compel at 4. FDA had explained to GTCR in detail why FDA cannot disclose the unredacted submissions under the protective order including statutory and regulatory requirements to redact TSI and CCI.

marketing authorization applicants or marketing authorization holders), rather than FDA, would be the appropriate source of this information.

GTCR's motion to compel now demands that FDA produce *all* submissions received by FDA from January 1, 2010, through the present, for medical devices that may use a lubricious coating. *See* Dkt. 154, Mot. to Compel at 2-3.

Argument

I. This Court Should Quash GTCR's Onerous Subpoena and Deny GTCR's Motion to Compel.

Federal Rule of Civil Procedure 45(d)(3)(A)(iv) provides that "the court . . . must quash or modify a subpoena that . . . subjects a person to undue burden." This court has not established a specific test for determining undue burden under Fed. R. Civ. P. Rule 45(d)(3)(A)(iv). Rather, this court considers a variety of factors including: (1) relevance; (2) the burden imposed; and, (3) "whether the information sought is readily obtainable from another, more convenient, less burdensome (but equally reliable) source[.]" *In re Outpatient Med. Ctr. Emp. Antitrust Litig.*, No. 21 C 305, 2024 U.S. Dist. LEXIS 161479, *12 (N.D. Ill. 2024); *Salas v. 3M Co.*, No. 08 C 1614, 2008 U.S. Dist. LEXIS 124993, *2 (N.D. Ill Aug. 28, 2008). "A party moving to quash has the burden of demonstrating that an undue burden exists." *Allstate Ins. Co. v. Electrolux Home Prods.*, No. 16 C 4161, 2017 U.S. Dist. LEXIS 189229 (N.D. Ill. Nov. 15, 2017).

Under Fed. R. Civ. P. 26, "the discovery sought must not only be relevant, but it must be proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." *Motorola Sols., Inc. v. Hytera Communs. Corp*, 365 F. Supp. 3d 916, 924 (N.D. Ill. 2019).

A. GTCR's Subpoena Poses an Undue Burden on FDA.

1. GTCR's Subpoena Is Directing FDA to Review Millions of Pages of Material Across all Submissions from January 1, 2010, to Present.

In total, GTCR's Subpoena would require FDA to review an estimated 350 million pages of material, requiring an estimated seven million agency hours, as described below. GTCR asks for all submissions from FDA through January 1, 2010, to present for any device that may use a lubricious coating. This request covers approximately 100,000 device submissions. Ex. B, Nipper Decl. ¶ 21. GTCR's requested documents may be located in one of three storage applications: Document Manager (DocMan), Image2000 Plus (Image), and CEntry. *Id.* ¶ 4. FDA staff would need to download each submission from its respective storage application. *Id.* ¶ 27.

Even though GTCR is interested in lubricous coating information in the submissions, FDA's Center for Devices and Radiological Health's ("CDRH") Submission Support staff would still need to manually review each entire premarket submission or supplement because there is a lack of standardized information or format included in the original submission as well as supplement documents. Ex. B, Nipper Decl. ¶ 27. Manual review is needed because using a "search" function would not be inclusive or comprehensive. *Id.* ¶ 27. There is no data filter or search method that would identify all lubricious coatings because proprietary names or other unique descriptors for that specific device characteristic may be used instead. *Id.* ¶ 27.

The average page count for a PMA submission (original) is 36,000 pages. Ex. B, Nipper Decl. ¶ 13. The average 510(k) submission contains 2,150 pages. *Id.* ¶ 18. The average De Novo submission contains on average 3,500 pages. *Id.* ¶ 16. Therefore, when taking even the conservative *median* page length across these three submissions (3,500) and multiplying it across the approximately 100,000 submissions, this Subpoena asks FDA to review approximately 350 *million* pages of material. *Id.* ¶ 26. Based on data from 2020-2024, CDRH's Division of

Information Disclosure ("DID") staff can review approximately 150 pages of documents per hour. Ex. C, Wallace Decl. ¶ 17. As discussed in Denise Wallace's declaration, DID conducts three independent rounds of review to ensure accuracy of the redactions. *Id.* ¶ 17. Therefore, it would take FDA staff approximately *seven million* hours to redact all the submissions, and this estimate does not include FDA's time to locate, gather, and produce the submissions.

2. GTCR's Request to Limit Submissions to the Product Codes Would Require, at Minimum, FDA to Collect and Review Twenty Million Pages, Requiring over 400,000 Agency Hours to Redact Requested Documents.

GTCR's suggestion to limit the request to submissions for the product codes listed in Appendix A of the Subpoena does little to change FDA's burden. FDA still would need to review over 20 million documents. It also does not significantly alter the resources needed to fully process the request. Ex. B, Nipper Decl. ¶ 23.

Of the product codes provided in Appendix A, approximately 6,370 are PMA submissions (including 111 original PMAs and 6,259 supplements). Ex. B, Nipper Decl. ¶ 25. The average page count for PMA submissions is 36,000 pages and 1,300 pages for supplements. *Id.* ¶ 13. Therefore, GTCR is asking FDA staff to review approximately 12,132,700 pages (excluding PMA reports). *Id.* ¶ 25.

There are approximately 3,800 510(k) submissions that fall into the product codes provided in Appendix A. Ex. B, Nipper Decl. ¶ 24. The average 510(k) contains 2,150 pages. *Id.* ¶ 24. Therefore, GTCR is asking FDA to review approximately 8,170,000 pages related to the 510(k) submissions. *Id.* ¶ 24. There is one De Novo submission that fall into the product codes provided in Appendix A. This submission has 2,475 pages. *Id.* ¶ 25.

As mentioned *supra*, DID staff can review approximately 150 pages of documents per hour and conducts three rounds of redaction review. Ex. C, Wallace Decl. ¶ 17. Therefore, it would take FDA staff over 406,000 hours to review and redact all the submissions for the product codes

listed in Appendix A of the Subpoena. On this basis, FDA has established that GTCR's Subpoena is unduly burdensome under Fed. R. Civ. P. 45(d)(3)(A)(iv) because the agency is unable to expend between 400,000 and 7,000,000 agency hours to respond to the Subpoena.

3. FDA Cannot Produce Requested Records Without Permission from Information Owners.

Before producing a submission, FDA would reach out to obtain consent from information owners before it produces their third-party records containing trade secret and confidential commercial information. After the initial redactions are completed, DID staff would issue Pre-Disclosure Notifications ("PDNs") to information owners to solicit their input on whether disclosure, as currently redacted, would cause substantial competitive harm. Ex. C, Wallace Decl. ¶ 7; 21 C.F.R. § 20.61(e)(1). GTCR argues that FDA can alleviate the need to reach out to individual owners of the medical device submissions by issuing a notice by publication under 21 C.F.R. § 20.61(e)(1). Dkt. 154, Mot. to Compel at 13-14. Under 21 C.F.R. § 20.61(e)(1), when FDA receives a request for records and "determines that disclosure may be required, [FDA] will make reasonable efforts to notify the submitter about these facts . . . If [FDA] must notify a large number of submitters, notification may be done by posting or publishing a notice[.]" FDA has discretion to issue a notice by publication and declines to do so in this case not only for the same reasons it originally objected to in the Subpoena, but also due to the complex scientific nature and sensitivity of the documents, the potential for inadvertent disclosure of TSI and CCI, and the need for submitters' input regarding their customary and actual treatment of the information at issue. Ex. C, Wallace Decl. ¶ 23; *see also Food Mktg. Inst. v. Argus Leader Media*, 588 U.S. 427, 440 (2019) ("At least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is "confidential" within the meaning of [FOIA] Exemption 4."). Given this, and

consistent with FDA's prior practice, FDA would provide the owner of each medical device submission an opportunity to review FDA's redactions before producing any documents to the requester, or GTCR in this case.

B. GTCR's Subpoena is Not Relevant to Its Claims or Proportional to the Needs of the Underlying Litigation.

GTCR's Subpoena is not proportional to the needs of the case because the Subpoena demands medical device submissions in their entirety when only a small portion of the submissions are relevant to the case. A third-party subpoena must conform to the requirements of Fed. R. Civ. P. 26(b)(1), meaning it must be both relevant to a party's claims or defenses and be proportional to the needs of the case. *See S.E.C. v. Laura*, No. 18 Civ. 5075, 2020 WL 5152873, at *2 (E.D.N.Y. Aug. 31, 2020). Rule 26(b)(2)(C)(i) requires the court to "limit the frequency or extent of discovery" otherwise allowed by these rules or by local rule if it determines that: "(i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive." When discovery is sought from non-parties, "the Court should be particularly sensitive to weighing the probative value of the information sought against the burden of production on the nonparty." *Cohen v. City of N.Y.*, No. 05 C 6780, 255 F.R.D. 110, 117 (S.D.N.Y. 2008) (quotations omitted). A party issuing a subpoena under Rule 45 must "take reasonable steps to avoid imposing undue burden or expense" on the non-party. *See* Fed. R. Civ. P. 45(d)(1); *Strike 3 Holdings, LLC v. Doe*, 331 F.R.D. 14, 17 (E.D.N.Y. 2019). A court "must enforce this duty and impose an appropriate sanction . . . on a party . . . who fails to comply." Fed. R. Civ. P. 45(d)(1); *Saint-Jean v. Emigrant Mortg. Co.*, No. 11 C 2122, 2015 WL 13735434, at *3 (E.D.N.Y. Oct. 7, 2015).

GTCR is only interested in a small sliver of information related to lubricious coating(s) that may be mentioned in any given medical device submission. However, GTCR requests the

entirety of numerous medical device submissions, including all supplements and associated master files. "Relevance focuses on the claims and defenses in the case, not its general subject matter." *Motorola Sols., Inc. v. Hytera Communs. Corp*, 365 F. Supp. 3d at 924. The claims and defenses here focus on understanding the lubricious coatings market and "whether the proposed acquisition will create anticompetitive effects." Dkt. 154, Mot. to Compel at 7. Depending on the type of submission, a medical device submission can contain detailed descriptions about the medical device, risk-management documentation, clinical studies, and proposed labeling. Ex. B, Nipper Decl. ¶¶ 9, 14, 17, and 19. While the *entire* medical device submission is within the broadest subject matter of this case (*i.e.*, medical devices), the submission in its entirety does not focus on the claims or defenses in this case, which is focused solely on lubricious coatings. Further, the *entire* medical device submission is not proportional to the needs of this case, much less the *entire* medical device submissions for between 10,171 (Appendix A product codes) to approximately 100,000 submissions (original subpoena request).

Contrary to GTCR's assertions, FDA is *not* a "complete source" of the information sought; only information owners are. FDA may not have lubricious coating supplier information, nor can FDA guarantee current or accurate information. For example, when medical devices are cleared under the 510(k) program or granted under the De Novo program, the marketing authorization holder would submit a new application to CDRH to determine whether any changes to the device may have affected its safety and effectiveness. Ex. B, Nipper Decl. ¶ 28. Instead, it is the marketing authorization holder's burden to remain compliant with its marketing authorization. For example, a marketing authorization holder may have modified a lubricious coating without informing CDRH, if the holder determined the change did not affect the safety or effectiveness of

the device. *Id.* ¶ 28. Thus, the information owner, rather than FDA, would have this complete information. *Id.* ¶ 28.

C. GTCR's Subpoena Seeks Non-Public Information that FDA Is Prohibited from Disclosing.

This court should deny the motion to compel and quash GTCR's Subpoena because it seeks unredacted medical device submissions that would disclose TSI and CCI, and FDA is prohibited from disclosing such information. Under Fed. R. Civ. P. 45(d)(3)(B), a court may quash a subpoena when compliance requires "disclosing a trade secret or other confidential research, development, or commercial information." As discussed *supra*, medical device submissions contain TSI and CCI, and the information GTCR is interested in, *i.e.*, lubricious coating information within the third-party submissions, is expected to be TSI and/or CCI. Ex. C, Wallace Decl. ¶ 15; Ex. B, Nipper Decl. ¶ 28.

There are potential civil and *criminal* penalties for federal employees who violate the Trade Secrets Act.[5] Ex. C, Wallace Decl. ¶ 19. The Federal Food, Drug, and Cosmetic Act ("FD&C Act") also prohibits the release of TSI or CCI except under circumstances not appliable here. 21 U.S.C. § 331(j); Ex. C, Wallace Decl. ¶ 19.

GTCR argues that the documents produced by FDA need not be redacted for TSI[6] and CCI because the protective order, Dkt. 61, will protect the information sought by the Subpoena. GTCR relies, in part, on *Meridian Labs., Inc. v. Oncogenerix USA, Inc.*, No. 18 CV 6007, 2021 U.S. Dist.

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[5] *See Jerome Stevens Pharms. v. FDA*, 319 F. Supp. 2d 45 (D.D.C. 2004), *aff'd in part and rev'd in part*, *remanded*, 402 F.3d 1249 (D.D.C. 2005) (seeking $1.345 billion in damages from FDA for releasing alleged TSI about the drug Unithroid).

[6] Contrary to GTCR's assertion that *Grupo Petrotemex, S.A. De C.V. v. Polymetrix AG*, No. 16-cv-2401 (SRN/HB), 2018 U.S. Dist. LEXIS 183965, at *7 (D. Minn. Oct. 26, 2018) applied to production of documents with trade secrets, that case only concerned documents with CCI. Dkt. 154, Mot. to Compel at 12.

LEXIS 200712 (N.D. Ill. Jan. 6, 2021), *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, No. 14 CV 7748, 2014 U.S. Dist. LEXIS 151602 (N.D. Ill. Oct. 27, 2014), and *Feature Films Servs., Inc. v. Arts & Ent. Network Corp.*, No. 91 CV 459, 1991 WL 290677, at *1 (N.D. Ill. Jan. 13, 1991), where the court held the protective orders in the underlying cases were sufficient to address disclosure of certain confidential information possessed by private parties. However, *Meridian Labs*, *Methodist Health Servs. Corp.*, and *Feature Films Servs., Inc.* are distinguishable from this case; in those cases, the court compelled disclosure of information from non-governmental entities, which are not bound by the Trade Secrets Act (18 U.S.C. § 1905) or other statutes specifically prohibiting disclosure of CCI and TSI by the federal government and its employees, such as 21 U.S.C. § 331(j).

As FDA previously explained to GTCR, the protective order applicable to the named parties in this case does not, and indeed cannot, relieve FDA of its *statutory* obligations not to publicly release protected information. Even under a protective order, FDA would need GTCR to provide a waiver from every information owner before disclosing such documents without redactions. The Trade Secrets Act, FD&C Act, the Freedom of Information Act, and FDA's regulations do *not* have exceptions for releasing protected and privileged information under a protective order, and the protective order does not provide a basis for FDA to disclose TSI and CCI that is strictly prohibited from disclosure. *See* Dkt. 61. Given that the submissions were provided to FDA from medical device companies that are neither parties to the underlying action nor covered by the existing protective order, CDRH's DID office determined that the protective order does not provide a sufficient basis to authorize the release of documents containing third-party information.

Ex. C, Wallace Decl. ¶ 22.[7] Overall, FDA cannot make a determination on behalf of each of the owners of the information that the protective order is sufficiently strong to protect each individual owner's trade secret information and confidential commercial information.[8] It is of utmost importance that FDA protects each individual owner's TSI and CCI as a matter of policy because FDA has an institutional interest in companies continuing to submit detailed and highly confidential information, including trade secret information, with confidence that FDA will protect their information.

D. GTCR's Subpoena Must Comply with FDA's *Touhy* Regulations.

GTCR's Subpoena also failed to comply with the agency's *Touhy* regulations. Courts have long recognized that federal agencies may promulgate regulations placing appropriate limits on demands for agency documents in third-party civil litigation. The United States Supreme Court expressly recognized this in *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951). FDA has

[7] Unlike *Buergofol GmbH v. Omega Liner Co., Inc.* and *Grupo Petrotemex, S.A. De C.V. v. Polymetrix AG*, where Customs and Border Protection failed to articulate why producing the information under the respective protective order would be improper, FDA has articulated in this case why producing medical device submissions under the protective order would be improper and statutorily prohibited. No. 22 C 4112, 2025 U.S. Dist. LEXIS 52522, at *19 (D.S.D. Mar. 19, 2025); No. 16 C 2401, 2018 U.S. Dist. LEXIS 183965, at *7 (D. Minn. 2018).

[8] GTCR's reliance on *Albany Molecular Research, Inc. v. Schloemer*. 274 F.R.D. 22 (D.D.C. 2011), is misplaced. The posture of this case is very different from *Schloemer*. In *Schloemer*, the plaintiff issued a third-party subpoena to FDA requesting *one* drug application submitted by PGxHealth as well as subsequent related documents concerning the drug. The defendant to the underlying action, along with the non-party owner of the information, PGxHealth, moved to quash the subpoena to FDA pursuant to Fed. R. Civ. P 45(c)(3)(B)(i). *Id.* at 25. *Schloemer* helps illustrates why FDA reaches out to the third-party owners of the protected information, in part, because third-party owners are in the best position to determine whether they would be harmed by the disclosure and explain that harm (or lack thereof) to the court. However, even in *Schloemer*, where the subpoena was much narrower in scope compared to GTCR's Subpoena, absent a waiver, FDA would still be required to review and redact non-public information before producing to the plaintiff.

promulgated such regulations, known as "*Touhy* regulations," which are set forth at 21 C.F.R. Part 20.

Yet, GTCR asks the court to require FDA to produce at least 10,000 medical device submissions, with up to thousands of pages per submission, without redacting protected information. Ex. B, Nipper Decl. ¶ 21. This request conflicts with FDA's regulations. *See SEC v. Selden*, 445 F. Supp. 2d 11, 14 n.6 (D.D.C 2006) (rejecting a third-party's argument that he was entitled to immediate access to the documents and holding he "must wait for the FDA to process his subpoenas under its *Touhy* regulations"). Under 21 C.F.R. § 20.2(a), a subpoena *duces tecum* shall comply with rules governing public disclosure established in subpart D.[9] Subpart D to Part 20 prohibits disclosure of TSI, CCI, and personally identifiable information ("PII"). 21 C.F.R. §§ 20.61(c), 20.63(a). To prevent disclosure of this material, FDA staff must identify and complete page-by-page, line-by-line reviews of any requested document to redact such exempt information. Ex. C, Wallace Decl. ¶ 13. Although 21 C.F.R. § 20.61 permits disclosure of TSI and CCI under limited circumstances, as noted *supra*, releasing such exempt information under a protective order is not an enumerated circumstance.

Consequently, GTCR's Subpoena should be quashed insofar as it conflicts with 21 C.F.R. Part 20. *See Edwards v. United States Dep't of Justice*, 43 F.3d, 312, 317 (7th Cir. 1994) ("*Touhy* is part of an unbroken chain of authority that supports the [agency's] contention that a federal

[9] Unlike *SEC v. Selden*, 445 F. Supp. 2d at 12-13, where FDA objected to a third-party subpoena and requested plaintiff file its request for documents pursuant to the Freedom of Information Act, here, FDA has made no such objection nor request. FDA can, and does, produce documents in response to third-party subpoenas in compliance with its *Touhy* regulations. However, the burden imposed by producing such documents in this case is extremely onerous, unduly burdensome, and neither relevant nor proportional to the needs of this case.

employee cannot be compelled to obey a subpoena, even a federal subpoena, that acts against valid agency regulations.").

E. GTCR Failed to Obtain the Requested Records from All Available Sources.

GTCR failed to seek the information requested from other, available sources. When subpoenaing a non-party, the requesting party "must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena." Fed. R. Civ. P. 45(d)(1). GTCR has failed this obligation. All the documents and information GTCR seeks originally came from third parties, not FDA. Ex. C, Wallace Decl. ¶ 24; *see also* Dkt. 154, Mot. to Compel at 14 (GTCR "seeks *only* materials submitted *by* medical device applicants *to* the FDA."). Unlike FDA, who may not have all the requested information, or may have outdated and inaccurate information related to lubricious coatings, Ex. B, Nipper Decl. ¶ 28, the information holders should have this information. Ex. C, Wallace Decl. ¶ 24. Additionally, unlike FDA, medical device companies are not governed by disclosure limitations such as the Trades Secret Act and other governing statutory prohibitions on disclosure like 21 U.S.C. § 331(j) (Ex. C, Wallace Decl. ¶ 24), and those companies are in a much better position to protect their trade secrets and confidential information. GTCR has never explained why they cannot seek the submissions directly from the original source, the owners of the medical device submissions.

Indeed, FDA has publicly available databases to identify individual medical device submissions, which can be sorted by product code and submission type.[10] Ex. C, Wallace Decl. ¶ 24. The databases, as well as the zip files, contain information including, but not limited to, the

[10] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfmon.

Although the 510(k) Premarket Notification database is limited to 500 devices that meet the search criteria, FDA provides access to the zip files, which contains all the medial devices for the time frame indicated. *See* https://www.fda.gov/medical-devices/510k-clearances/downloadable-510k-files.

applicant's name, contact information, and product code. GTCR could download the releasable 510(k) submissions on FDA's website. This information is sufficient for GTCR to identify the owners of the medical device submissions and directly request the information from them.

A district court may reject a subpoena if it seeks discovery that is "unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; [or when] the party seeking discovery has had ample opportunity to obtain the information by discovery in the action[.]" Fed. R. Civ. P. 26(b)(2). Here, thousands of submissions, if relevant, can be obtained from a more convenient and appropriate source, *i.e.*, the actual owners of the information.

Conclusion

For the foregoing reasons, this court should quash GTCR's Subpoena in its entirety and deny GTCR's motion to compel.

Respectfully submitted,

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Exhibit A

April 22, 2025

VIA ELECTRONIC MAIL

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Re: Subpoena - *Federal Trade Commission v. GTCR BC Holdings, LLC and Surmodics, Inc.*
Civil Action No. 1:25-cv-02391

Dear Matthew Yelovich:

This letter responds to the third-party subpoena that you issued to the United States Food and Drug Administration (FDA) on April 14, 2025, in the above-referenced case. It sets forth our initial objections to the subpoena pursuant to Rule 45(d)(2)(B) of the Federal Rules of Civil Procedure.[1]

Your subpoena requests three broad categories of documents, from January 1, 2010, to the present, including:

1. For all 510(k), PMA, or De Novo submissions received by FDA from January 1, 2010, through the present regarding any devices that may use a Lubricious Coating, including, but not limited to, devices associated with any Product Code in Appendix A, documents, and databases sufficient to identify, for each 510(k), PMA, or De Novo:
    a. Any Lubricious Coating(s) used on the device; or if no such Lubricious Coating is used on the device, a statement to that effect.
    b. Supplier(s) of each Lubricious Coating used on the device.
    c. Name and/or unique identifier of Lubricious Coating(s) used on the device.
    d. Curing method of each Lubricious Coating used on the device (if specified in by 510(k), PMA, or De Novo)
    e. The relevant 510(k) Number, PMA Number or De Novo Number associated with the submission.
    f. The decision and decision date associated with the submission.
2. For all devices that may use a Lubricious Coating, including, but not limited to, those associated with any Product Codes provided in Appendix A, all documents constituting, including, included with, or referenced within all 510(k), PMA, and De Novo submissions from January 1, 2010, through the present. These materials include, but are not necessarily limited to:
    a. 510(k) submissions to the FDA.

[1] Because FDA has not completed its review of potentially responsive documents, this written objection may not include all possible bases for objection. FDA reserves the right to assert later, that additional bases exist for objecting to the disclosure of the requested documents.

   b. PMA submissions to the FDA.
   c. De Novo submissions to the FDA.
   d. All letters of authorization from a MAF holder or by their designated agent(s) included in a 510(k), PMA, or De Novo submission to the FDA.
3. All documents constituting, including, or included with all MAF submissions received from January 1, 2010, through the present for Lubricious Coatings, including but not limited to:
   a. All MAFs, in whatever form submitted to FDA.

Although FDA has not yet had the opportunity to collect and review all the documents that may be responsive to your request, based on our initial assessment, it appears that the Federal Rules of Civil Procedure, federal law, and discovery privileges may prevent FDA from disclosing some portion of the requested documents to you.

Below, I explain the grounds for these objections based on our preliminary evaluation.

<u>The Date of Production is Unreasonable</u>

The subpoena, as drafted, based on our experience with similar requests, will require a significant amount of time and resources to collect and review potentially responsive documents. Accordingly, FDA objects to our subpoena because it fails to allow a reasonable amount of time to comply. *See* Fed. R. Civ. P. 45(d)(3)(A)(i). Because potentially responsive documents may contain information that is privileged or otherwise protected from release or disclosure, FDA must carefully review every document to determine whether any or all of the information must be withheld from production. The subpoena, however, directs the production of documents no later than 5:00 pm on April 28, 2025.

FDA is currently responding to a significant increase in third-party document requests, including Freedom of Information Act ("FOIA") requests, Congressional requests, and other subpoenas related to its core mission. FDA is employing a queue approach to properly accommodate the processing of these document requests. See *Watts v. S.E.C.*, 482 F.3d 501, 509 (D.C. Cir. 2007), citing to *Exxon Shipping v. Dep't. of Interior*, 34 F.3d 774, 780 (9th Cir. 1994), Circuit Judge Kavanaugh notes that "discovery under [Rule 45] must properly accommodate the smooth functioning of government operations" (internal quotation marks omitted).

Given the existing document production demands on FDA and the time needed to review the potentially large number of documents responsive to your subpoena, directing FDA to respond to your subpoena no later than 5:00 PM on April 28, 2025, is unreasonable.

<u>Prohibition on FDA's Disclosure of Trade Secret and Confidential Commercial Information</u>

FDA is prohibited from producing any portion of the documents you requested that contain trade secret information entitled to protection, if any, under 21 U.S.C. § 331(j). In addition, the Trade Secrets Act, 18 U.S.C. § 1905, prohibits the release of trade secret and confidential commercial information ("CCI") unless otherwise authorized by law. Further, FDA regulations provide that trade secret and CCI are not available for public disclosure. *See* 21 C.F.R. § 20.61. Accordingly, FDA is unable to produce any responsive information that would reveal trade secret and/or confidential research, development, or commercial information. See also Fed. R. Civ. P. 45(d)(3)(B)(i).

The extent to which the agency will be required to redact responsive documents prior to production, as well as the speed at which FDA will be able to produce these documents, largely depends upon whether the parties in the referenced case are authorized and have entered an acceptable protective order that permits FDA to produce to you trade secret and CCI that FDA would otherwise need to identify and withhold. In the event that a protective order is not in place or is inadequate to ensure the protection of trade secret or CCI belonging to non-parties, you may speed the production of responsive documents, if any, by obtaining an appropriate waiver from the owner of the trade secret or CCI that authorizes, with specificity, FDA to provide this information to you for use in the referenced case.

Objections Based on the Deliberative Process and Other Privileges

Based on FDA's experience with similar requests, we expect that some responsive documents may contain materials reflecting FDA's pre-decisional deliberative process and are thus privileged and not subject to production under the subpoena. *See* Fed. R. Civ. P. 45(d)(3)(A)(iii). The deliberative process privilege protects materials that are part of the decision-making process of a government agency. The privilege extends to, among other things, "documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." Dep't of the Interior v. Klamath Water Users Protective Ass'n, 532 U.S. 1, 8 (2001) (quoting NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 150 (1975)); see also Judicial Watch v. Dep't of Justice, 20 F. Supp. 3d 260, 268 (D.D.C. 2014).

Courts have relied on the deliberative process privilege to shield from production pre-decisional government documents that have been requested pursuant to a subpoena. See, e.g., Chem. Weapons Working Group v. EPA, 185 F.R.D. 1, 3-4 (D.D.C. 1999) (denying motion to compel production where release of the subpoenaed documents would likely stifle candid communication within the agency, lead to public confusion, and violate the integrity of the decision-making process). The release of such documents would discourage frank and open discussions within the agency and disrupt FDA's ability to engage in the decision-making process. Accordingly, FDA objects to your requests to the extent they seek pre-decisional deliberative documents.

Similarly, to the extent that the subpoena seeks disclosure of materials that are or contain attorney-client communications, attorney work product, personal privacy information, privileged investigatory files, and/or other protected information, we object to disclosure on those bases as well.

Responsive Documents Are Available from Another Source

FDA also objects to the extent that the subpoena requests documents which, even if contained in FDA files, are available elsewhere. Specifically, you request documents that may belong to, or relate to products of, the parties and non-parties in the underlying litigation. Your request for these documents is objectionable under Rule 45, Rule 26(b)(2)(C), and 21 C.F.R § 20.51, as they could be obtained more easily from a party to the underlying litigation, thus sparing the use of taxpayer resources.

The Subpoena is Overly Broad and Unduly Burdensome

On April 1, 2025, FDA experienced a significant reduction in force (RIF), including in the Center for Devices and Radiological Health's Division of Information Disclosure Policy, which is the office responsible for locating, collecting, and reviewing potentially responsive records in response to your subpoena. FDA is still evaluating the impact the RIF may have on FDA's immediate operations, which may include an impact on FDA's capacity to handle and respond to

document subpoenas. Given the Agency's limited resources to respond to third party litigations, where FDA is not a party and the documents, as mentioned above, can be obtained by GTCR BC Holding, LLC and Surmodics, Inc. through other avenues, the burden is a particularly significant factor.

The subpoena is also overly broad and unduly burdensome. *See* Fed. R. Civ. P. 45(d)(1), (d)(3)(A)(iv); 21 C.F.R § 20.50. As noted, your subpoena is quite expansive. As discussed above, your requests encompass documents that may contain pre-decisional communications, trade secret, and/or CCI protected under applicable statutes, regulations, and privileges from release or disclosure. Thus, responding to your subpoena as currently drafted would likely require a significant amount of time to collect and review many potentially responsive documents for possible production. Using a significant amount of FDA employee time to prepare these documents for potential production in litigation to which the United States is not a party would deprive FDA of valuable resources and put a strain on the agency's resources. Accordingly, the subpoena is objectionable, pursuant to Rule 45 and 21 C.F.R § 20.50, as overly broad and unduly burdensome.

The Information Sought is Neither Relevant nor Proportional to the Needs of the Case

Relatedly, a Rule 45 subpoena can only be used to "obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1); see also Davis v. Cox, 2019 WL 1783066, at *9 (E.D. Mich. Mar. 29, 2019) (applying the Rule 26 standard of discoverability to a Rule 45 subpoena). While some subset of information requested in the subpoena may fall within the scope of discovery under Rule 26, you have failed to articulate how the expansive request is relevant and proportional to the needs of the case. For example, you requested "All documents constituting, including, or included with all MAF submissions received from January 1, 2010, through the present for Lubricious Coatings, including but not limited to: All MAFs, in whatever form submitted to FDA." Surely not every record in this sweeping category proportional to the needs of the case. FDA objects to the subpoena for lack of relevancy and proportionality.

Conclusion

Notwithstanding the foregoing, FDA is committed to working with you to resolve this matter and to produce documents in a manner that is consistent with federal law, regulations and procedures and the agency's commitments and obligations in other matters and does not subject the agency to an unreasonable burden. To process your requests more expeditiously, however, we strongly encourage you to narrow the scope of your requests and prioritize the types of documents that you are requesting.

If you have any further questions, please contact Tobi Erskine at FDAInfoShare@fda.hhs.gov.

Sincerely,

Mark A. Barnes -S
Digitally signed by Mark A. Barnes -S
Date: 2025.04.22 09:27:28 -04'00'

Mark Barnes
Acting Director
Division of Information Disclosure
DID/ODIGA/OMES/OC/FDA

Exhibit B

Declaration of Joshua Nipper

I, Joshua Nipper, hereby declare as follows:

1. I am the Division Director of the Division of Regulatory Programs 1 (Submission Support), in the Office of Regulatory Programs ("ORP"), Office of Product Evaluation and Quality ("OPEQ"), within the U.S. Food and Drug Administration's ("FDA") Center for Devices and Radiological Health ("CDRH"). My office is located at White Oak Building 66, 10903 New Hampshire Avenue, Silver Spring, MD 20993. I have been the Division Director of the team responsible for overseeing Submission Support since May of 2019. Prior to my role as Division Director, I served as Director of the premarket approval ("PMA") program staff from 2016 to 2019.
2. In my capacity as a Division Director, I am able to search, provide certain data collection, and download and send CDRH records to CDRH's Division of Information Disclosure ("DID") staff for review, redaction, and disclosure.
3. I have access to premarket submissions, and any corresponding supplements, master files ("MAFs"), or other documentation (including required postmarket reporting or other notices/supplements), that are located in one of the below-named databases, as received by CDRH from the information owner. I am responsible for collecting numerous records in different locations requested by a third-party subpoena, my responsibilities entail searching for records under the Center's custody and control to identify documents and other information that may be responsive to particular information requests or subpoena requests. CDRH's DID then reviews the requested records to determine whether, before being made for public disclosure they should be redacted in part, or withheld in their entirety, under FOIA and other applicable disclosure laws. CDRH's DID is then responsible for further reviewing, redacting and disclosing any potentially responsive records.

4. I am familiar with, and understand the records structure for marketing authorization submissions received by the CDRH, including those related to the PMA program; the premarket notification ("510(k)") program; the De Novo Classification Request ("De Novo") program, the investigational device exemption ("IDE") program, the Humanitarian Device Exemption ("HDE") program, the classification/reclassification program, and all other marketing authorization and clearance pathway programs which are tracked and recorded in CDRH's storage and tracking applications. The submission storage applications include Document Manager (DocMan), Image2000 Plus (Image), and CEntry. Submission Support staff know how to search for, locate, and download specific applicant-submitted documents, including master files, internal review communications, and external agency communications to the submitters of any such submissions. My staff and I are familiar with and understand how to search the publicly available Medical Device Databases.[1]
5. On June 18, 2025, GTCR BC Holdings, LLC, filed its Opposed Motion to Compel FDA to Comply with its Subpoena. I submit this declaration in support of Non-Party FDA's Memorandum in Opposition to GTCR's Motion to Compel and in Support of Its Motion to Quash. The statements made in this declaration are based on my personal knowledge and official records or information available to me in my official capacity.
6. The purpose of this declaration is to: (a) describe an overview of FDA's regulation of medical devices; (b) describe the general procedures for searching and collecting documents responsive to third-party subpoenas; (c) describe the volume and scope of the records sought in Defendant's April 14, 2025, subpoena request; (d) explain why FDA is not a complete source for information related to lubricious coatings; and, (e) explain that information related to the manufacturing process contains trade secret information ("TSI").

OVERVIEW OF FDA'S REGULATION OF MEDICAL DEVICES

7. CDRH is the Center within FDA that is responsible for regulating medical devices and radiation-emitting products. To market a medical device in the United States,

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm (510k database); https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm (PMA database); https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm (classification database).

manufacturers must obtain authorization from FDA through one of the marketing pathways, which include, but is not limited to, PMA, 510(k), and De Novo Classification Requests. Medical devices are categorized into one of three classes (I, II, or III), based on the degree of risk they present. As device class increases from class I to class II to class III, the regulatory controls also increase, with class I devices subject to the least regulatory control, and class III devices subject to the most stringent regulatory control. Generally, the appropriate submission type is identified within the product classification. The product classification may be obtained from the publicly available Product Classification database.[2]

8. FDA has approximately 10,000 premarket submissions relating to medical devices associated with the eighty-one (81) separate Product Codes provided in Appendix A to the Subpoena since January 1, 2010.

9. A PMA application is a comprehensive scientific, regulatory submission made by a device manufacturer to FDA that includes extensive information about the medical device to demonstrate the safety and effectiveness of a medical device. A PMA approval is needed before a Class III medical device, the most highly regulated class of medical devices, can legally be marketed in the United States. A PMA is the most stringent type of device marketing application required by the FDA. The contents of an original PMA are specified by 21 C.F.R. § 814.20, and include:

    a. A comprehensive device description section containing data and information.

    b. A non-clinical laboratory studies section, which may include information on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, electromagnetic compatibility, electrical safety, software verification and validation, and other laboratory or animal tests as appropriate. The specific testing sections for each PMA are dependent on the type of medical device being proposed.

    c. A clinical investigations section, which includes study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all

[2] The publicly available Product Classification database can be found here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

individual subjects, results of statistical analyses, and any other information from the clinical investigations. Any investigation conducted under an Investigational Device Exemption (IDE) must be identified as such.

d. A description of the methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device.

10. Information pertaining to a lubricious coating could be included in the device description information, the performance testing, biocompatibility testing, manufacturing information (or all of the above) of a PMA application.
11. As described by 21 C.F.R.§ 814.39, applicants must submit a PMA supplement to request approval for any PMA modification that may impact the safety or effectiveness of the device absent certain circumstances. The type of PMA supplement is dependent on the change being requested; with supplements and reports or notices to the agency defined in 21 U.S.C. § 379i(4) and (5). PMA supplements could be submitted to add, modify, or change the manufacturing procedures of a lubricious coating.
12. As described by 21 C.F.R. § 814.84, a holder of an approved PMA must also submit a periodic (typically annual) report summarizing changes made to the device along with other information updates. Changes to a lubricous coating could be made and reported under a PMA annual report if such a change does not impact the safety or effectiveness of the device (*e.g.*, to a non-patient contacting material). If FDA determines safety or effectiveness of the device is impacted, the Agency instructs the applicant to submit a supplement, creating further records.
13. Based on previous calculations for other CDRH official business, the average original PMA submission contains approximately 36,000 pages, the average PMA supplement contains approximately 1,300 pages, and the average PMA report contains approximately 300 pages.
14. A De Novo submission is for a medical device for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which is there no legally marketed predicate device. De Novo

classification is a risk-based classification process. The contents of a De Novo submission are specified by 21 C.F.R. § 860.220, and include:

a. Administrative information, such as the device's intended use, prescription use or over-the-counter use designated, etc.
b. A device description, which includes but is not limited to technology, proposed conditions of use, accessories, and components.
c. A complete discussion of why general controls or general and special controls provide reasonable assurance of the safety and effectiveness of the device, and what special controls, if proposing a class II designation, would allow the Agency to conclude there is reasonable assurance the device is safe and effective for its intended use.
d. Clinical data (if applicable) that are relevant to support reasonable assurance of the safety and effectiveness of the device.
e. Non-clinical data including bench performance testing, information on the reprocessing and sterilization, shelf-life testing, biocompatibility, software verification and validation, electrical safety and electromagnetic compatibility, and other laboratory or animal tests as appropriate. The specific testing sections for each De Novo submission are dependent on the type of medical device being proposed.
f. A description of the probable benefits of the device when compared to the probable or anticipated risks when the device is used as intended.

15. Information pertaining to a lubricious coating could be included in the device description information, the performance testing, or biocompatibility testing (or all of the above) of a De Novo submission.
16. Based on previous calculations for other CDRH official business, the average De Novo submission contains approximately 3,500 pages.
17. A 510(k) premarket submission must demonstrate that a medical device is substantially equivalent to a legally marketed device (predicate device) that is not subject to a PMA. See 21 U.S.C. § 360(k); 21 C.F.R. Part 807, Subpart E. A device is substantially equivalent if it has the same intended use and technological characteristics as a predicate device, or if it has different technological characteristics but is as safe and effective as the

predicate device. 21 U.S.C. § 360c(i). A 510(k) premarket submission includes information including, a detailed device description, an intended use statement, proposed labeling, substantial equivalence discussion, and performance data (if applicable). Information pertaining to a lubricious coating could be included in the device description information, the performance testing, or biocompatibility testing (or all of the above) of a 510(k) submission.

18. Based on previous calculations for other CDRH official business, the average 510(k) submission contains approximately 2,150 pages.

19. MAFs are used by a submission applicant to use another party's product (e.g., ingredient, subassembly, or accessory) or facility in the manufacture of the device. To ensure that a sound scientific evaluation may be made of the PMA, IDE, or other device submission, the review of data and other information related to the other party's product, facility, or manufacturing procedures is required. The other party, while willing to allow FDA's confidential review of this information, may not want the IDE, 510(k), or PMA applicant to have direct access to the information. To help preserve the trade secrets of the ancillary medical device industry and at the same time facilitate the sound scientific evaluation of medical devices, FDA established the device master file system. In addition, a master file may be considered when several applications may be submitted for different products which may use a common material or process, etc., such as the same sterilization method.

THE RECORDS SOUGHT BY THE SUBPOENA

20. On April 14, 2025, Cleary Gottlieb Steen & Hamilton sent FDA a third-party subpoena, which sought the following records:

a) For all 510(k), PMA, or De Novo submissions received by FDA from January 1, 2010, through the present regarding any devices that may use a Lubricious Coating, including, but not limited to, devices associated with any Product Code in Appendix A, documents, and databases sufficient to identify, for each 510(k), PMA, or De Novo:

i. Any Lubricious Coating(s) used on the device; or if no such Lubricious Coating is used on the device, a statement to that effect.

ii. Supplier(s) of each Lubricious Coating used on the device.

iii. Name and/or unique identifier of Lubricious Coating(s) used on the device.

iv. Curing method of each Lubricious Coating used on the device (if specified in by 510(k), PMA, or De Novo)

v. The relevant 510(k) Number, PMA Number, or De Novo Number associated with the submission.

vi. The decision and decision date associated with the submission.

b) For all devices that may use a Lubricious Coating, including, but not limited to, those associated with any Product Codes provided in Appendix A, all documents constituting, including, included with, or referenced within all 510(k), PMA, and De Novo submissions from January 1, 2010, through the present. These materials include, but are not necessarily limited to:

i. 510(k) submissions to the FDA.

ii. PMA submissions to the FDA.

iii. De Novo submissions to the FDA.

iv. All letters of authorization from a MAF holder or by their designated agent(s) included in a 510(k), PMA, or De Novo submission to the FDA.

c) All documents constituting, including, or included with all MAF submissions received from January 1, 2010, through the present for Lubricious Coatings, including but not limited to:

i. All MAFs, in whatever form submitted to FDA.

21. The subpoena would require, at minimum, Submission Support staff to research and review all PMA, De Novo, and 510(k) submissions, including all MAFs (included if cited by an applicant), received by FDA from January 1, 2010, to present. Submission Support staff would need to do an exhaustive search; requiring thorough review of each document contained in each premarket submission or supplement to determine whether the document is responsive, including those which may contain handwritten content from the earlier temporal range of the request. For the Product Codes provided in Appendix A alone, this would amount to over 10,000 submissions; 'including but not limited to' opens the range of potential device submissions to over 100,000. This approximation would not include PMA annual reports or notifications.

22. Each year, FDA receives approximately 3,500 510(k) applications, 30-40 PMA submissions, 30-40 panel track supplements, and 70 De Novo submissions.

23. OPEQ cannot determine the exact number of documents and individual pages within each submission without manually opening and downloading each submission. OPEQ does not have the time or resources to pull over 10,000 submissions to provide an exact number of documents that would be responsive to the request for those submissions in Appendix A alone.
24. Based on previous calculations for other CDRH official business, OPEQ can provide the following estimate of the volume of this request. There are approximately 3,800 510(k) submissions that fall into the product codes provided in Appendix A. The average 510(k) contains 2,150 pages. Using the average pages contained in 510(k) submissions, there are approximately 8,170,000 pages related to the 510(k) submissions.
25. Of the product codes provided in Appendix A, approximately 6,370 are PMA submissions (including 111 original PMAs and 6,259 supplements). Using the average pages contained in PMA submissions, there are approximately 12,132,700 pages (excluding PMA reports). There is only one De Novo submission that fall into the product codes provided in Appendix A. This De Novo has 2,475 pages. In total, using the approximate average values for each submission type, there are approximately 20,305,175 pages for the submissions that fall under was product codes listed in Appendix A. These page number estimates exclude any MAFs that may be cited by reference in these submissions.
26. When taking the median page length across these three submissions (i.e., 510(k), De Nova, and PMA) (3,500) and multiplying it across the approximately 100,000 submissions, this Subpoena asks FDA to review approximately 350,000,000 pages of material.
27. The requester has subpoenaed a wide range of information related to lubricious coating, and thus, even if OPEQ limited their search to documents in a submission discussing lubricious coating, Submission Support staff would need to manually review each entire premarket submission or supplement because there is a lack of standardized information or format included in the original submission, as well as the supplement documents. My staff would not be able to capture the full scope of the request from database searches alone, and the result will most certainly not be inclusive or comprehensive. Variability in search results is a certain outcome due to search method and filter limitations. For

example, a 'lubricious coating' may be referred to by a submission applicant by a proprietary name or another descriptor for that specific device characteristic. There is no proper data filter or search method in the above-named databases that would comprehensively identify all lubricious coatings across all submission types. For a comprehensive search to identify all the information requested about lubricious coating in a medical device, Submission Support staff would need to review each submission. After responsive documents within the submissions are identified, Submission Support staff would need to download each individual document and upload it to a shared folder within the Agency. Furthermore, errors and inaccuracies in optical character recognition (OCR), particularly for older files, can cause searches to miss files or pages that may contain information pertaining to a lubricious coating.

28. Additionally, information sought by the subpoena, including but not limited to, methods of coating, application, and curing are part of the applicant's manufacturing method and are expected to be protected trade secret information that, unless publicly disclosed by the applicant, would require the agency to reach out to each information owner for a waiver to disclose to any party. *See* 21 C.F.R. §20.61(e)(1). Regarding the subpoena's request for coating supplier information, we may not have this information, nor could we guarantee current or accurate information since it is the marketing authorization holder's burden to stay in compliance. For devices cleared under the 510(k) program or granted under the De Novo program, marketing authorization holders themselves submit a new application to CDRH prior to making changes to their device that may affect safety and effectiveness. However, a marketing authorization holder may have modified a lubricious coating without informing CDRH if they have determined this change may not impact the safety or effectiveness of the device. For devices approved under the PMA or HDE pathway, the marketing authorization holder is required to submit timely annual reports apprising CDRH of any change not previously submitted as a PMA supplement.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my information and belief.

Executed on July 3, 2025

Joshua C. Nipper -S

Digitally signed by Joshua C. Nipper -S
Date: 2025.07.03 11:56:09 -04'00'

Joshua Nipper
Division Director
Division of Regulatory Programs 1 (Submission Support)
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices & Radiological Health
U.S. Food and Drug Administration

Exhibit C

Declaration of Denise Wallace

I, Denise Wallace, hereby declare as follows:

1. I am the Assistant Director of the Special Projects Disclosures Team, Division of Information Disclosure ("DID") within the U.S. Food and Drug Administration's ("FDA") Center for Devices and Radiological Health ("CDRH").[1] My office is located at White Oak Building 32, 10903 New Hampshire Avenue, Silver Spring, MD 20993. I have been Assistant Director of the Special Projects Disclosures Team since December 2023. Prior to this role, I served as a Director and Assistant Director of two other Freedom of Information Act offices within the U.S. Department of Health and Human Services.
2. I have supervisory authority over the Special Projects Disclosures Team within DID, which, among other responsibilities, handles document production requests for third-party subpoenas and other litigation. DID staff is responsible for researching, reviewing, redacting, and disclosing CDRH records in accordance with applicable exemptions, privileges or protections, including but not limited to, the Trade Secrets Act 18 U.S.C. § 1905, the Freedom of Information Act 5 U.S.C. § 552, the Privacy Act 5 U.S.C. § 552a, the Federal, Food, Drug, and Cosmetic Act , 21 U.S.C. §§ 331(j), 360(j), and FDA regulations found within 21 C.F.R. §§ 20.61, 20.63.
3. I am familiar with and understand the data structure for premarket submissions received by the CDRH, including those related to the premarket approval ("PMA") program; the premarket notification ("510(k)") program; the De Novo ("De Novo") Classification Request program, the investigational device exemption ("IDE") program; and the classification/reclassification program, and tracked in CDRH Document Manager (DocMan) and Image 2000 Plus (Image) and know how to search for and locate

[1] For awareness, FDA is currently undergoing reorganization and title and office names may change.

premarket submission documents. I am also familiar with and understand how to search the publicly available Medical Device Databases.[2]

4. In my capacity as Assistant Director, I have access to premarket submissions received by the CDRH through one of the above-named storage applications. For documents not stored in one of the above-named storage applications or for complex searches, I would ask for documents from CDRH's Office of Product Evaluation and Quality ("OPEQ"). I am responsible for redacting and disclosing documents, including premarket submissions, in third-party subpoenas on behalf of CDRH.
5. I submit this declaration in support of Non-Party FDA's Memorandum in Opposition to GTCR's Motion to Compel and in Support of its Motion to Quash to the June 18, 2025, Opposed Motion of GTCR BC Holdings, LLC to Compel U.S. Food and Drug Administration to Comply with Subpoena in this matter. The statements made in this declaration are based on my personal knowledge and official records or information available to me in my official capacity.
6. The purpose of this declaration is to (a) describe the general procedures for responding to third-party subpoenas; (b) describe the volume and scope of the redactions of the records sought in the subpoena request; (c) explain FDA's statutory and regulatory obligations to redact trade secret and confidential commercial information from documents before publicly releasing them.

DID'S PROCEDURE FOR RESPONDING TO THIRD-PARTY SUBPOENAS

7. For complex requests, DID sends a request to OPEQ to conduct a search for responsive documents. After the search has been performed and the records have been retrieved by OPEQ, the documents are sent to DID. DID then conducts a line-by-line, page-by-page review of each responsive document to determine whether any exemptions or privileges apply. Any exempt material is redacted or withheld. After the initial review, DID staff generally issues pre-disclosure notifications ("PDNs") to the information owners pursuant to 21 C.F.R. § 20.61(e). A supervisor and/or a team lead ensures agreed-upon

[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm (510k database); https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm (PMA database); https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm (classification database).

redactions of exempt information and privileges have been applied properly and that all non-exempt information has been released. Finally, DID prepares copies of the responsive documents, as redacted, and sends them to the requester.

8. CDRH document reviews are time consuming and complex. DID's document reviews are performed by reviewers with medical device experience, with years or decades of experience in reviewing documents. This knowledge is necessary to identify issues unique to FDA document review. Identification of redactions during FDA document review is significantly more complex than identification of redactions during private practice document review. It is FDA's practice to redact protected material at the time it is identified. This process of identifying issues, pausing to review to redact, and then continue the review is intrinsically slower than private practice review.
9. For third parties, FDA document reviewers often spend a significant amount of time using their specialized technical knowledge in determining whether information is publicly available. This includes extensive Internet searches and the review of many pages of documents external to the documents under review. Determining commercial worth can involve similar searches and reviews, and necessitate contacting the firms involved, who are in the best position to determine the presence or absence of confidential commercial information.

THE RECORDS SOUGHT BY THE SUBPOENA

10. On April 14, 2025, Cleary Gottlieb Steen & Hamilton sent FDA a third-party subpoena, which sought the following records from FDA:

    a) For all 510(k), PMA, or De Novo submissions received by FDA from January 1, 2010, through the present regarding any devices that may use a Lubricious Coating, including, but not limited to, devices associated with any Product Code in Appendix A, documents, and databases sufficient to identify, for each 510(k), PMA, or De Novo:
        i. Any Lubricious Coating(s) used on the device; or if no such Lubricious Coating is used on the device, a statement to that effect.
        ii. Supplier(s) of each Lubricious Coating used on the device.
        iii. Name and/or unique identifier of Lubricious Coating(s) used on the device.

iv. Curing method of each Lubricious Coating used on the device (if specified in by 510(k), PMA, or De Novo)

v. The relevant 510(k) Number, PMA Number or De Novo Number associated with the submission.

vi. The decision and decision date associated with the submission.

b) For all devices that may use a Lubricious Coating, including, but not limited to, those associated with any Product Codes provided in Appendix A, all documents constituting, including, included with, or referenced within all 510(k), PMA, and De Novo submissions from January 1, 2010, through the present. These materials include, but are not necessarily limited to:

i. 510(k) submissions to the FDA.

ii. PMA submissions to the FDA.

iii. De Novo submissions to the FDA.

iv. All letters of authorization from a Master File ("MAF") holder or by their designated agent(s) included in a 510(k), PMA, or De Novo submission to the FDA.

c) All documents constituting, including, or included with all MAF submissions received from January 1, 2010, through the present for Lubricious Coatings, including but not limited to:

i. All MAFs, in whatever form submitted to FDA.

11. The subpoena would require, at minimum, FDA to research and review all PMA, De Novo, and 510(k) submissions, including MAF submissions, received by FDA from January 1, 2010, to present.

12. FDA would need to do an exhaustive page-by-page review of each document contained in each premarket submission to determine whether the document was responsive and to provide the specific information requested by the subpoena.

13. FDA would need to review each document collected and do an exhaustive line-by-line, page-by-page review of each document to redact any applicable exemptions and privileges, as the requested documents are likely to contain information that is not publicly releasable.

14. Even though the requester is interested in specific information related to lubricious coating, DID would still need to review the entire premarket submission. OPEQ preliminary identifies a document that may be responsive. Then, DID reviews the document to ensure it is responsive to the request.
15. Most of the information sought by the subpoena, including but not limited to, the supplier(s) of the lubricious coating used on the device, the name and/or unique identifier of the lubricious coating used on the device, and the curing method of each lubricous coating, is expected to be trade secret and/or confidential commercial information.

DID'S HANDLING OF THE APRIL 14, 2025, SUBPOENA

16. After DID receives the documents from OPEQ in a shared folder, DID uploads the documents into FDA's database, FOIAXpress, to conduct document review, which takes between 8-10 weeks based on the current queue times.[3]
17. Based on data from 2020 to 2024, DID averages 150 pages per hour. However, variables may impact review speed, including the length of the documents, the complexity of the issues and law, and the prevalence of privileged material. Given the potential civil and criminal liability for releasing privileged or exempt information, each document is reviewed by three different reviewers: the initial reviewer, a team lead, and a supervisor.
18. For FDA to review, research, redact, and disclose the requested documents it would take an overburdensome amount of DID's resources. For example, using the average 150 pages per hour, reviewing the approximate average pages for each submission type that falls under Appendix A of the subpoena, as discussed in Nipper Decl. ¶¶ 21-25, it would take approximately 406,103.5 hours for DID redact the approximately 20,305,175 requested pages in this case.[4] Based on the information above, the subpoena, even under the limited search to submissions that fall under the product codes listed in Appendix A, would consume a great amount of FDA's already strained and limited resources.

[3] For awareness, FDA's contract with FOIAXpress ends on August 17, 2025. If FDA switches to another database, this could add additional time.
[4] This is based on the three rounds of review: the initial review and two additional quality control reviews by the team lead and supervisor.

DIDP MUST REDACT DOCUMENTS FOR EXEMPTIONS AND PRIVILEGES

19. The Trade Secrets Act, which applies to all employees of the United States, including FDA employees, prohibits the disclosure of trade secret and confidential commercial information unless otherwise authorized by law. 18 U.S.C. § 1905. There are potential civil and criminal penalties for federal employees who violate the Trade Secrets Act.[5] The Federal Food, Drug, and Cosmetic Act also prohibits the release of trade secret or confidential commercial information except under circumstances not appliable here. 21 U.S.C. § 331(j). All medical device submissions contain trade secret and CCI.
20. FDA's disclosure regulations applicable to all agency records are found in 21 C.F.R. Part 20. Per 21 C.F.R. § 20.61(c), "[d]ate and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret, or confidential commercial or financial information are not available for public disclosure." "Commercial or financial information that is privileged or confidential" is defined by regulation to mean "valuable data or information which is used in one's business and is a type of customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs." 21 C.F.R. § 20.61(b).
21. Public policy also favors redacting trade secret and confidential commercial information from responsive documents before releasing. The intent of the applicable disclosure provisions, and of FDA's regulations, is to safeguard important interests of both the government and those who submit confidential information. These provisions ensure that federal agencies can obtain necessary and reliable commercial and financial information from the parties they regulate. Such protections are important for FDA, which is responsible for protecting public health by ensuring the safety, efficacy, and security of products it regulates, and for advancing public health by helping to speed innovations that make products more safe, more effective, and more affordable. Unauthorized disclosure of a third-party entity's confidential information may undermine the willingness of regulated parties to provide the agency information and seriously impair FDA's ability to perform its critical mission.

[5] *See Jerome Stevens Pharms. v. FDA*, 319 F. Supp. 2d 45 (D.D.C. 2004), *aff'd in part and rev'd in part*, *remanded*, 402 F.3d 1249 (D.D.C. 2005) (seeking $1.345 billion in damages from FDA for releasing alleged trade secret information about the drug Unithroid).

22. The protective order in this matter does not, and cannot, relieve FDA of its obligation to avoid public release of protected material. The Trade Secrets Act, Federal Food, Drug, and Cosmetic Act, the Freedom of Information Act, and FDA's regulations do not have an exception for releasing protected and privileged information under a protective order. Further, FDA cannot make a determination on behalf of each information owner that the protective order is sufficiently strong to protect their trade secret and confidential commercial information. Overall, CDRH's DID office determined that the protective order in this case does not provide a sufficient basis to authorize the release of documents of third-party entity's information that are neither parties to the underlying action nor covered by the existing protective order.
23. FDA has discretion to issue a notice by publication under 21 C.F.R. § 20.61(e)(1) and declines to do so in this case due to the complex scientific nature and sensitivity of the documents, the potential for inadvertent disclosure of trade secret and CCI, and the need for submitters' input regarding their customary and actual treatment of the information at issue.[6]
24. Information related to lubricious coating can be obtained by the defendant requesting such information directly from the medical device marketing authorization applicants or marketing authorization holders. The requester can pull a list of applicants or authorization holders and their contact information from FDA's publicly available Medical Device Databases.[7] Unlike FDA, private entities are not bound by the statutory prohibitions on disclosure noted above, such as the Trade Secrets Act.

[6] *Food Mktg. Inst. v. Argus Leader Media*, 588 U.S. 427, 440 (2019) ("At least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is "confidential" within the meaning of [FOIA] Exemption 4.").
[7] https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-and-clearances

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my information and belief.

Executed on July 03, 2025

Denise F. Wallace -S

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